

## REMARKS

Claims 26-30, 32-35, and 40-49 were pending in the application. By this amendment, claims 26, 33, 40, 45, and 48 have been amended, and claim 30 has been cancelled. Accordingly, claims 26-29, 32-35, and 40-49 are now pending.

The following remarks are in response to the rejections of claims and other matters set forth in the Office Action.

### I. Claim Objection

Claim 40 was objected to due to being dependent upon a cancelled claim. This oversight has been corrected by the present amendment to the claim. Accordingly, Applicants request withdrawal of this objection.

### II. Claim Rejected Under 35 U.S.C. § 112

Claim 33 was rejected due to insufficient antecedent basis for the term “the second tissue contact point.” This oversight has been corrected by the present amendment to the claim. Accordingly, Applicants request withdrawal of this rejection.

### III. Claims Rejected Under 35 U.S.C. § 102

Claims 45-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by Suzuki et al. (US 2002/0111534). Without acceding to any of the Examiner’s stated grounds for rejecting the claims, Applicants respond as follows.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Claims 45 and 48 recite an apparatus having, inter alia, an overtube, a first catheter configured for insertion through the overtube, and an anchor delivery system adapted to deliver an anchor assembly (claim 45) or a flexible delivery catheter extending through the overtube (claim 48). Each of these claims has been amended to further recite that the overtube has a steerable distal region “comprising at least one steering wire.”

This is a significant feature of the claimed apparatus for at least the reason that the independent steering capability of the overtube eliminates the need for the apparatus to rely upon an endoscope (or other device) for steering. This feature, in combination with the other features recited in claims 45 and 48, patentably distinguish the claimed apparatus from the Suzuki publication and the other cited art.

More particularly, the Suzuki publication describes an apparatus that includes a sheath 84, a first endoscope 2 and a second endoscope 6 insertable through the sheath 84, and a holding device 11 (that includes a sheath 14) that is insertable through the first endoscope 2. (See Suzuki, Fig. 1, paragraphs 0038-39). The sheath 84 is not described as being steerable, and does not include a steering wire. Instead, in the Suzuki device, all steering and control is provided by the first endoscope 2 and second endoscope 6. The Office Action contends that “a user is able to manually steer the distal end of the overtube [sheath 84] so that the overtube comprises a steerable distal region.” Applicants strongly disagree with the unreasonable construction of the claim term “steerable” that underlies this contention. Nevertheless, in an effort to expedite prosecution of the application, Applicants have amended claims 45 and 48 in the manner discussed above to recite that the overtube comprises “at least one steering wire.” This feature is not included in the Suzuki device, nor is there any teaching or suggestion in the Suzuki publication (or in the art in general) that the Suzuki device should be modified to include this feature.

Accordingly, because at least these limitations recited in claims 45 and 48 are not taught or suggested by the Suzuki publication, there can be no anticipation of those claims, or of the claims dependent therefrom. Applicants respectfully request withdrawal of the rejections of claims 45 through 49.

#### IV. Claims Rejected Under 35 U.S.C. § 103

Claims 26-30, 32-35, and 41-44 were rejected under 35 U.S.C. § 103 as being unpatentable over the Suzuki publication in view of Jaffe (US 2002/0161281). Without acceding to any of the Examiner’s stated grounds for rejecting the claims, Applicants respond as follows.

To establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there

must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Claim 26 recites an apparatus having, inter alia, an overtube, a first catheter, and an anchor delivery system adapted to deliver an anchor assembly and secure a tissue fold. Similar to claims 45 and 48 discussed above, claim 26 has been amended to further recite that the overtube includes “at least one steering wire providing a steering capability for a distal region of the overtube.” As noted above, this is a significant feature of the claimed apparatus for at least the reason that the independent steering capability of the overtube eliminates the need for the apparatus to rely upon an endoscope (or other device) for steering. This feature, in combination with the other features recited in claim 26, patentably distinguish the claimed apparatus from the combination of Suzuki and Jaffe.

The deficiencies of the Suzuki device are discussed above. The Jaffe publication does not provide any teaching or suggestion that corrects these deficiencies. The Jaffe guide tube 14 is not steerable. Instead, the guide tube 14 is constructed to allow it to be advanced over an endoscope in a flexible state and to assume the curve formed by the steerable endoscope. (See Jaffe, Figures 11A-E, paragraphs 0037, 0051). Nor is there any teaching or suggestion in either of the Suzuki or Jaffe publications (or the art in general) that either of the devices should be modified to include a steering wire providing a steering capability for a distal region of an overtube.

Accordingly, because at least these limitations recited in claim 26 are not taught or suggested by the Suzuki or Jaffe publications, the Office Action fails to establish a prima facie case of obviousness of claim 26 or the claims dependent therefrom.

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Examiner: Lang, Amy T.

Attorney Docket No.: USGINZ02513

Applicants respectfully request withdrawal of the rejections of claims 26-30, 32-35, and 41-44.

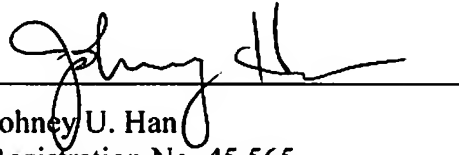
Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, but rather as an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02513**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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